IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA

JAN K. VODA, M.D.,	)	
	)	
Plaintiff and Counterclaim Defendant,	)	
	)	
v.	)	No. CIV-03-1512-L
	)	
CORDIS CORPORATION,	)	
	)	
Defendant and Counterclaim Plaintiff.	)	

O R D E R

Plaintiff, Dr. Jan K. Voda, is the holder of three patents issued by the United States Patent and Trademark Office. Patent No. 5,445,625 ("the '625 patent") protects his invention of an angioplasty guide catheter and reflects the catheter "in a relaxed state prior to insertion in the cardiovascular system." The two remaining patents (the '213 and the '195 patents) cover plaintiff's inventive technique for using the catheter to perform angioplasty. In addition to method claims, the '195 patent also includes claims that focus on the catheter as it appears in the aorta. On October 30, 2003, plaintiff filed this action seeking damages for alleged infringement of the three patents by defendant, Cordis Corporation.

This matter is before the court on the parties' motions for summary judgment. Summary judgment is appropriate if the pleadings, affidavits, and depositions "show

that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Any doubt as to the existence of a genuine issue of material fact must be resolved against the party seeking summary judgment. In addition, the inferences drawn from the facts presented must be construed in the light most favorable to the nonmoving party. Board of Education v. Pico, 457 U.S. 853, 863 (1982). Nonetheless, a party opposing a motion for summary judgment may not simply allege that there are disputed issues of fact; rather, the party "must set forth *specific* facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e) (emphasis added). *See also*, Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). "[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Anderson, 477 U.S. at 249-50 (citations omitted). In addition, "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In determining whether a party has made a sufficient showing, the court must examine the showing in light of the party's substantive evidentiary burden. Anderson, 477 U.S. at 254.

The undisputed facts establish that the '625 patent was issued on August 29, 1995. Thereafter, Dr. Voda sought and received the '213 and '195 patents on July 4, 2000 and November 5, 2002, respectively. All three patent applications claimed priority under 35 U.S.C. § 120 to an application filed on January 23, 1991. Plaintiff asserts Cordis' XB catheters infringe the following sixteen claims:

'625 Patent

> 1. A femoral approach angioplasty guide catheter adapted for selective catherization of a left main coronary artery within a cardiovascular system comprising:
>
> an elongate flexible tubular member in a relaxed state prior to insertion in the cardiovascular system further comprising in consecutive arrangement:
>
> a first straight proximal portion extending distally from a proximal end of the tubular member;
>
> a second straight portion joined to the first straight portion and having a length of about 1.5 to 2.5 centimeters;
>
> a tertiary curved portion defining a junction of the first straight portion and the second straight portion and defining a vertex of an obtuse angle of 130° to 150° between the first and second straight portions;
>
> a secondary curved portion joined to the second straight portion and having an arcuate curvature of about 150° to 180° and a radius of curvature of about 1 centimeter;
>
> a third straight portion joined to the secondary curved portion;
>
> a fourth straight portion joined to the third straight portion and having a distal end defining a terminal distal tip of the tubular member; and

a primary curved portion a junction of the third straight portion and the fourth straight portion and defining a vertex of an obtuse angle of 140° to 160° between the third and fourth straight portions,

wherein the interiors of the tertiary curved portion and every curve portion distal thereof, including the secondary curved portion and the primary curved portion, all generally face each other,

wherein the first straight portion, second straight portion, third straight portion, and fourth straight portion all lie in generally the same plane, the third straight portion and the fourth straight portion extending slightly out of plane to the extent that the fourth straight portion overlaps the first straight portion, and

wherein the length of the fourth straight portion is approximately equal to the sum of the length of the third straight portion and the radius of curvature of the secondary curved portion.

2. The catheter of claim **1** wherein:

the second straight portion has a length of about 1.5 centimeters, the third straight portion has a length of about 0.5 to 1.0 centimeters, and the fourth straight portion has a length of about 1.5 to 2.0 centimeters.

* * *

5. The catheter of claim **1** wherein the third straight portion has a length of about 0.5 to 2.0 centimeters.

6. The catheter of claim **1** wherein the fourth straight portion has a length of about 1.5 to 3.0 centimeters.

7. The catheter of claim **1** wherein the sum of the lengths of the fourth straight portion and the third straight portion and the radius of curvature of the secondary curved portion is about 3.5 to 6.0 centimeters.

Exhibit 1 to Declaration of John M. DiMatteo in Support of Cordis' Motion for Summary Judgment at 32-34 [hereinafter cited as "Cordis Motion"].

'213 Patent

> 1. A method for advancing a catheter through the aorta and into a coronary ostium, the aorta having an arch and an inner wall opposite the ostium, comprising the steps of:
>
> providing a catheter including an elongate catheter body having a proximal end and a distal end and having a central lumen from the proximal end to the distal end adapted to slidably receive a therapeutic catheter, the catheter body including a tip at the distal end of the catheter body adapted to removably lodge in the coronary artery ostium;
>
> advancing the catheter body distal end through the aortic arch; and
>
> engaging the aorta inner wall with a portion of the catheter body such that when the distal end of the catheter is positioned in the ostium, the catheter body engages the opposite wall of the aorta along a line having a length of about 1.5 cm or greater.
>
> 2. A method in accordance with claim **1**, wherein the ostium is the left coronary ostium.
>
> 3. A method in accordance with claim **2**, further comprising the step:
>
> > further advancing the catheter distal end into the coronary artery ostium while engaging the aorta inner wall with the body portion.
>
> 4. A method for advancing a catheter through an aorta and into a branch artery, the aorta having an arch and an inner wall opposite the branch artery, comprising the steps of:

providing a catheter including a tubular member having a shaft, an integral profiled portion, and an integral, substantially straight tip portion, the tip portion being adapted to axially engage the branch artery;

wherein the catheter profiled portion comprises, in order from the shaft portion to the tip portion, a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend;

advancing the catheter tip portion through the aorta; and

engaging the branch artery with the tip portion, such that when the tip portion is engaged with the branch artery, the profiled portion engages the aorta wall opposite the branch artery along a line.

5. A method in accordance with claim **4**, further comprising the step:

further advancing the catheter tip portion into the branch artery while engaging the aorta inner wall with the profiled portion.

Exhibit 2 to Cordis Motion at 30-32.

'195 Patent

1. An assembly for guiding the path of a therapeutic catheter, comprising:

an elongate tubular member including a proximal shaft portion, a profiled portion, and a substantially straight tip portion;

the profiled portion comprising, in order from the proximal shaft portion to the tip portion, a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend;

the first bend, the first substantially straight leg, the second bend, the second substantially straight leg, and the third bend being disposed within a chamber of an aorta;

a distal end of the tip portion being disposed within an ostium defined by the aorta;

the first substantially straight leg seating against a wall of the aorta opposite the ostium of the coronary artery; and

the elongate tubular member defining a lumen extending from a distal end of the elongate tubular member to a proximal end of the elongate tubular member, wherein the lumen is constructed and arranged to receive the therapeutic catheter.

2. A femoral approach angioplasty guide catheter adapted for selective catheterization of a coronary artery within a cardiovascular system including an aorta, comprising:

an elongate tubular member having a shaft, a profiled portion, and a substantially straight tip portion;

the catheter profiled portion comprising, in order from the proximal shaft portion to the tip portion, a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend;

wherein substantially the entire length of the first substantially straight leg seats against a wall of the aorta opposite an ostium of the coronary artery when a distal end of the tip portion is positioned within the ostium of the coronary artery.

3. An assembly for guiding the path of a therapeutic catheter through the aorta to an ostium of the coronary artery, comprising:

an elongate tubular member including a proximal shaft portion, a profiled portion, and a substantially straight tip portion;

means for engaging an ostium of the coronary artery;

means for seating against a wall of the aorta including a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend; and

the elongate tubular member defining a lumen extending from a distal end of the elongate tubular member to a proximal end of the elongate tubular member, wherein the lumen is adapted and configured to receive the therapeutic catheter.

4. A femoral approach angioplasty guide catheter adapted for selective catheterization of a coronary artery within a cardiovascular system including an aorta, comprising:

an elongate tubular member having a shaft, a profiled portion, and a substantially straight tip portion;

the catheter profiled portion comprising, in order from the proximal shaft portion to the tip portion, a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend;

wherein the first substantially straight leg comprises means for seating against a wall of the aorta opposite an ostium of the coronary artery when a distal end of the tip portion is positioned within the ostium of the coronary artery.

5. A method for guiding the path of a therapeutic catheter, comprising:

providing an elongate tubular member including a proximal shaft portion, a profiled portion, and a substantially straight tip portion;

wherein the profiled portion comprises, in order from the proximal shaft portion to the tip portion, a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend;

wherein the elongate tubular member defines a lumen extending from a distal end of the elongate tubular member to a proximal end of the elongate tubular member, wherein the lumen is adapted and configured to receive the therapeutic catheter therein;

disposing a distal end of the tip portion within an ostium the coronary artery; and

seating the first substantially straight leg against a wall of the aorta opposite the ostium of the coronary artery.

6. A method for guiding the path of a therapeutic catheter, comprising:

providing an elongate tubular member having a shaft, a profiled portion, and a substantially straight tip portion;

wherein the profiled portion comprises, in order from the proximal shaft portion to the tip portion, a first bend, a first substantially straight leg, a second bend, a second substantially straight leg, and a third bend; and

seating substantially the entire length of the first substantially straight leg against a wall of the aorta opposite an ostium of the coronary artery when a distal end of the tip portion is positioned within the ostium of the coronary artery.

Exhibit 3 to Cordis' Motion at 28-30.

Infringement analysis first requires proper construction of the claims at issue to determine their scope and meaning. *See* PC Connector Solutions LLC v.

SmartDisk Corp., 406 F.3d 1359, 1362 (Fed. Cir. 2005). Construction of claims is a question of law. Id. Once the claims have been construed, the analysis requires that the claim in question "be compared to the accused device or process." Id. It is at this second step that a determination of infringement is made; whether a device infringes literally or under the doctrine of equivalents is a question of fact. Lockheed Martin Corp. v. Space Sys./Loral, Inc., 324 F.3d 1308, 1318 (Fed. Cir. 2003). "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995). If even a single limitation is not present in the accused device, literal infringement does not exist as a matter of law. Such a device, however, can still be found to infringe a patent under the doctrine of equivalents. This doctrine provides that "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997). The doctrine recognizes

> that to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for – indeed encourage – the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.

Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607 (1950).

Prior to the *Markman*[1] hearing, the parties agreed to the definitions of the following terms:

Patent	**Term**	**Construction**
all	distal	Closer to the target site in a patient's body; farther from the nurse or doctor using the catheter.
all	proximal	Closer to the nurse or doctor using the catheter; farther from the target site in the patient's body.
all	catheter	A flexible, tubular medical device for insertion into canals, blood vessels, passageways or body cavities.
'625	tertiary	Third in order.
'625	to the extent	If or when.
'213	bend	A bend or curve.
'213, '195	lumen	The channel or bore running the length of the catheter.
'213, '195	ostium	The opening into a blood vessel.
'213, '195	aorta	The main trunk of a series of blood vessels which convey oxygenated blood to the tissues of the body and is comprised of the ascending aorta, the arch of the aorta, and the descending aorta.

[1]Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd 517 U.S. 370 (1996).

After the *Markman* hearing, the court issued an order construing the remaining disputed claim terms as follows:

Patent	**Disputed Term**	**Court's Interpretation**
'625	straight portion	Exhibiting no deviation from the vertical or horizontal.
'213	along a line	Contacting the aorta inner wall with a portion of the tube body such that when the end of the catheter lodges within the opening in the coronary artery, an about 1.5. cm or greater length of the tube body bears upon the wall of the aorta opposite the opening.
'213 & '195	substantially straight	A segment that deviates slightly, if at all, from the straight and that cannot be defined as a curve.

Plaintiff argues the Cordis XB catheters literally infringe each of the claims at issue. Cordis counters its catheters do not literally infringe the straight or substantially straight claims because the accused catheters do not have a "second straight portion" as required by the '625 patent or a "first substantially straight leg" as required by the '213 and '195 patents. Cordis contends it does not infringe Claims 1-3 of the '213 patent ("the engaging claims") because it does not instruct physicians to engage the wall of the aorta and there is nothing in the design of Cordis' catheters that will assure such engagement in every use.

Plaintiff's own expert witness establishes that the XB catheters do not literally infringe the '625 patent claims. Claim 1 requires three *straight* segments at the distal

end of the catheter. As defined by the court, a straight portion exhibits no deviation from the vertical or horizontal.[2] Jack C. Griffis, III, plaintiff's catheter engineering expert, admits "the Cordis XB catheter has a blended segment between the tertiary and secondary bends. This blended segment, when considered as a spline, represents an equivalent section as the Voda first *substantially* straight leg." Exhibit 48 to Plaintiff's Motion at Exhibit 1 at 6 (emphasis added). Mr. Griffis defines a spline as "a special curve defined piecewise by polynomials." Id. Likewise, during his deposition, Mr. Griffis conceded the XB catheters do not literally infringe either the '625 or the '195 patent.

> Q. The Court defined straight portion as used in the 625 patent as "exhibiting no deviation from the vertical or horizontal." . . . With that construction, your opinion is the accused Cordis XB catheters infringe only under the doctrine of equivalence?
>
> A. That's correct.
>
> Q. Also – and that is the 625 patent. Also, the Court construed substantially straight as "a segment that deviates slightly, if at all, from the straight and that cannot be defined as a curve." Under the 195 patent and the 1213 (sic). With that construction it's your opinion that the Cordis XB catheters 3.5, 4.0,

[2]Plaintiff's argument that "[t]here is potentially a genuine issue of material fact as to whether the [XB catheters have] 'straight' legs under the Court's construction" is nonsensical. Dr. Voda's Opposition to Cordis' Motion for Summary Judgment at 31. Plaintiff claims the catheters do not deviate from the horizontal when laid on a horizontal table top because "the entire catheter lies in the horizontal plane." Id. Likewise, he asserts "if the Cordis XB catheter is hung vertically, as in a cath lab, the entire catheter lies in a vertical plane." Id. Plaintiff's argument is flawed because the term "straight" does not refer to the catheter as a whole, but rather to discrete elements of the profiled portion of the catheter.

> 4.5, infringe under the doctrine of equivalence, correct?
>
> A. I believe so, yes. I think that is why I wrote my second supplemental.
>
> Q. Correct. You do not believe that they infringe literally? That's the 195 patent.
>
> A. Using the Court's construction.

Deposition of Jack Griffis, III, Exhibit 11 to Cordis' Motion at 226-27. This analysis applies with equal force to Claims 4 and 5 of the '213 patent which require "a first substantially straight leg". Cordis is therefore entitled to judgment that its catheters do not literally infringe the straight and substantially straight claims of the patents at issue.

Summary judgment must, however, be denied with respect to these claims under the doctrine of equivalents given the diametrically opposed evidence presented by the parties. Notwithstanding these fact issues, defendant contends plaintiff is estopped from asserting equivalent infringement based on the prosecution history of the '213 patent. During prosecution of that patent, Dr. Voda amended what are now Claims 1 and 4. Claim 1 was amended to reflect the length of engagement of the aortic wall, specifying "a length of about 1.5 cm or greater." Exhibit 5 to Cordis' Motion at 2. Claim 4 was amended to describe the shape of the profiled portion and to reflect that the profiled portion engaged the wall of the aorta "along a line." Id. Based on these amendments, defendant argues plaintiff is

estopped from asserting infringement by "catheters having curved portions similar to the accused XB catheters." Cordis' Motion at 16. While defendant focuses on the amendment to Claim 4 adding the description of the profiled portion, plaintiff argues that amendment was tangential to the purpose of the amendment, which was to distinguish prior art catheters. Plaintiff claims the distinction between his invention and the prior art focused not on the shape of the catheter, but rather on the length and location of the catheter's engaging the wall of the aorta. The amendment itself substantiates this assertion. In his submission to the Patent and Trademark Office, Dr. Voda distinguished prior art catheters on the grounds that

> his invention, unlike the catheters disclosed by Feiring, Bower and Danforth engages the wall of the aorta, *opposite the distal end of the catheter when the distal end of the catheter is positioned in the ostium*, along a line having a length of about 1.5 cm or greater. Each of the catheters disclosed by Feiring, Bower and Danforth engage the ascending aorta at a bend or curve along the catheter. None provide support *along a line of about 1.5 cm or greater*.

Exhibit 5 to Cordis' Motion at 3 (emphasis added). Whether prosecution history estoppel applies is a question of law for the court,[3] which in this case the court answers in the negative. As a matter of law, the court finds prosecution history estoppel is not applicable.

The court also finds Cordis is not entitled to summary judgment on the method claims of the '213 patent as genuine issues of material fact exist. While Cordis is

[3]Glaxo Wellcome, Inc. v. Impax Labs., Inc., 356 F.3d 1348, 1351 (Fed. Cir. 2004).

correct that as a seller of medical devices it does directly infringe the method claims, it can, however, be vicariously liable. Section 271(b) of Title 35 provides "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Likewise, § 271(c) imposes liability on "[w]hoever offers to sell or sells within the United States . . . [an] apparatus for use in practicing a patented process . . . knowing the same to be especially made or especially adapted for use in an infringement of such patent, an not a staple article or commodity of commerce suitable for substantial noninfringing use". 35 U.S.C. § 271(c). "Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement." Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993). In addition to direct infringement, plaintiff must demonstrate that Cordis "knowingly induced infringement and possessed specific intent to encourage another's infringement." Minnesota Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1305 (Fed. Cir. 2002), *cert. dismissed* 538 U.S. 972 (2003). Contributory infringement likewise requires proof of defendant's knowledge and that the devices have "no substantial non-infringing uses." Cross Med. Prod., Inc. v. Medtronic Sofamor Daneek, Inc., 424 F.3d 1293, 1312 (Fed. Cir. 2005) (citation omitted). Plaintiff has submitted sufficient evidence on all these elements to withstand summary judgment. Defendant cites Met-Coil Sys. Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 687 (Fed. Cir. 1986), for the proposition that Dr. Voda's use of XB catheters cannot demonstrate direct infringement. That case, however, is

inapposite. At issue in Met-Coil was whether a patent owner's sale of a machine useful only in practicing the claimed inventions constituted an implied license. Drs. Voda, Almany, and Hildner all testified they have used XB catheters; there is thus at least an issue of fact as to direct infringement. Furthermore, there is sufficient circumstantial evidence to create an issue of fact as to defendant's knowledge, active inducement, and whether the catheters have substantial non-infringing uses. Summary judgment is thus inappropriate. *See* Cross Med. Prod., Inc., 424 F.3d at 1314.

Cordis also argues the '213 patent is invalid as anticipated. Patents are entitled to a presumption of validity. 35 U.S.C. § 282. To overcome that presumption, Cordis must establish invalidity by clear and convincing evidence. Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1378 (Fed. Cir. 2005). Clear and convincing evidence is evidence that "produces in the mind of the trier of fact an abiding conviction that the truth of a factual contention is 'highly probable.'" Price v. Symsek, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (*quoting* Buildex, Inc. v. Kason Indus., Inc., 849 F.2d 1461, 1463 (Fed. Cir. 1988). A patent is invalid as anticipated only if every limitation in a claim is found in a single prior art reference. Nystrom v. TREX Co., Inc., 424 F.3d 1136, 1149 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 1654 (2006).

As the single prior art reference, defendant relies on an article written in 1969 by Martial G. Bourassa, M.D., Jacques Lesperance, M.D., and Lucien Campeau,

M.D. entitled "Selective coronary arteriography by the percutaneous femoral approach," that appeared in the October 1969 issue of *American Journal of Roentgenology Radium Therapy and Nuclear Medicine* ("the 1969 Bourassa article"). In particular, defendant points to Figure 2(B), which it contends "shows a catheter engaging the opposite wall of the aorta along a line greater than the 1.5 cm required by '213 patent claims 1-3." Cordis' Response Brief to Plaintiff's Motion for Partial Summary Judgment at 26. This conclusion, however, is sufficiently disputed by plaintiff to create a genuine issue of material fact. Summary judgment is thus inappropriate.

The court also concludes that plaintiff is not entitled to summary judgment that the patents in suit are not invalid or that Cordis induced and contributed to infringement of the method claims of the '213 patent. As noted above, genuine issues of material fact exist with respect to vicarious infringement and whether the 1969 Bourassa article teaches all of the elements of Claims 1-5 of the '213 patent. Likewise, genuine issues of material fact surround whether the Amplatz catheters embody all of the elements of claims 1-3 of the '213 patent. While the ultimate determination that an invention is obvious, and therefore unpatentable, is a legal conclusion, that conclusion is necessarily based on underlying findings of fact. *See* Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1164 (Fed. Cir. 2006). At this stage in the litigation, the court concludes too many factual issues exist for the court to

determine whether the defense of obviousness with respect to the '695 patent is valid.

In sum, Cordis' Motion for Summary Judgment of Non-Infringement of U.S. Patent Nos. 5,445,625, 6,083,213, and 6,475,195 and Invalidity of U.S. Patent No. 6,083,213 (Doc. No. 179) is GRANTED in part and DENIED in part. Plaintiff's Motion for Partial Summary Judgment that (1) the Patents in Suit are Not Invalid and (2) Defendant is Liable for Infringing Claims 1-3 of the '213 Patent (Doc. No. 171) is DENIED.

It is so ordered this 8th day of May, 2006.

Tim Leonard

TIM LEONARD
United States District Judge